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K013251

510(k) Summary

Applicant: CAIRE Inc.
Address: 3505 County Road 42 West
Burnsville, MN 55306-3803

Contact: Roger Briese
Bio-Medical Engineering Manager

Phone Number: (952) 882-5071
Facsimile Number: (952) 882-5175
E-Mail Address: roger.briese@chart-ind.com

Date: September 20, 2001

Device Name: Spirit 300
Device Class: II
Classification Panel: Anesthesiology
CFR Section: 868.5655
Product Code: BYJ

Legally Marked Device to Which Substantially Equivalency is Claimed:
Caire Stroller [FDA 510(k) #K800742]
Puritan Bennett HELiOS [FDA 510(k) #K993220]
DeVilbiss LP05PP [FDA 510(k) #K833994]

Description of the Device:
The Spirit 300 is a small, lightweight, liquid oxygen portable unit. The unit consists of a vacuum-insulated cryogenic dewar, a vaporizer coil, an economizer regulator, two pressure safety relief valves, a manifold, an electronic printed circuit board conserving device and a protective case. The dewar has a capacity and capability to store 0.3 liters of liquid oxygen. The vaporizer coil warms the oxygen gas to a suitable temperature, as it exits the dewar. The economizer regulator either draws gas from the dewar head space, if the internal pressure is above 20 PSI. If the internal pressure is below 20 PSI, the economizer regulator will draw liquid oxygen from the bottom of the dewar, which must then have to pass through a long vaporizing coil. The economizer regulator assures a longer duration time for the unit, because it allows the gas in the dewar head space to be used for oxygen delivery. The gas outlet of the economizer regulator connects with the manifold. Dependant on the flow selection setting, the manifold either delivers the gas to the conserving device PCB or diverts a 2 LPM continuos flow directly to the oxygen outlet. The continuos flow setting is labeled CF on the flow selector. The conserving device has equivalent settings for 1, 1.5, 2, 3, 4 and 5 LPM prescriptions. At the various conserving device settings, the outlet gas is delivered in quick pulse dosages just at the onset of patient inhalation. The amount of gas delivered (with each breath) is approximately 15 ml/LPM setting.

Intended Use of the Device:
The CAIRE Spirit 300 will provide a source of supplemental oxygen for ambulatory home healthcare patients, by vaporizing medical grade liquid oxygen and then dispensing it to the patient via an integral electronic conserving device. The Spirit 300 is neither a life sustaining nor life supporting device.

Technological Characteristics: CAIRE Spirit 300 vs. CAIRE Stroller
The main technical difference between these devices is that the Spirit 300 incorporates an integral electronic conserving device to deliver oxygen doses with patient inhalation, while the Stroller delivers oxygen in a continuous flow. The Spirit 300 is also smaller in both size and weight than the Stroller. However, the dewar design, plumbing style, fill connectors, relief safety valves and vent valves of these devices are either quite similar, if not common. With the method of oxygen delivery being the core technical difference, the non-clinical testing clearly shows that the Spirit 300 oxygenates similarly to the Stroller.

Technological Characteristics: CAIRE Spirit 300 vs. Puritan-Bennett HELiOS
The main technical difference between these devices is that the Spirit 300 incorporates an integral electronic conserving device to deliver oxygen doses with patient inhalation, while the HELiOS incorporates a pneumatic conserving device to deliver the oxygen doses. Other than this technical point, the Spirit 300 and HELiOS are quite similar in other technical/physical aspects. Again, the non-clinical testing clearly shows that the Spirit 300 oxygenates similarly (if not significantly better) than HELiOS.

Technological Characteristics: CAIRE Spirit 300 vs. DeVilbiss #LP05PP
The technical design of the Spirit 300 and the DeVilbiss #LP05PP are quite similar. The physical size of the two devices is different. The Spirit 300 is a 0.34L capacity unit, while the DeVilbiss #LP05PP is a 0.49L capacity unit. Specific to the conserving device, both devices are very similar in technical operation. Again, the non-clinical testing clearly shows that the Spirit 300 oxygenates similarly to the DeVilbiss product. Note the non-clinical testing indicated that the Spirit 300 is more sensitive than this DeVilbiss product. This explains why the Spirit 300 oxygenated a little better at the higher flow settings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2001

Caire, Inc.
c/o Mr. Mark Job
TÜV Product Service, Inc.
1775 Old Highway 8 NW, Suite #104
New Brighton, MN 55112-1891

Re: K013251
Spirit 300
Regulation Number: 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: Class II (two)
Product Code: 73 BYJ
Dated: December 7, 2001
Received: December 10, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

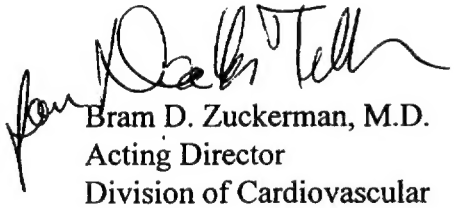
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013251

Device Name: SPIRIT 300

Indications For Use:

The CAIRE Spirit 300 will provide a source of supplemental oxygen for ambulatory home healthcare patients by vaporizing medical grade liquid oxygen and then dispensing it to the patient via an integral electronic conserving device. The Spirit 300 is neither a life sustaining nor life supporting device.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription ✓

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013251